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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,407	12/12/2001	Edward A. Rhad	END-795	3685

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,407

Applicant(s)

RHAD ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 - 12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 12/12/01 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Specification

1. The disclosure is objected to because of the following informalities: Page 4, line 20 states, “are se forth”; Page 7, line 18 seems to have a note to the drafter of the figures, line 27 states, “at he distal”, line 33 states “needle 20”; the elongated needle has previously been referred to with reference numeral 30; Page 8, line 17 states, “inner 22”, line 22 is spaced improperly, line 32 refers to a “left body half 40”, reference numeral 40 previously referred to a left body member; Page 10, lines 5 – 6 state, “the left body member 40 and right body member 40 and right body member 50”; Page 11, states, “in the art is sharp”. “Is sharp” appears to be added onto the end of the sentence. Page 11, lines 14, 15, 18, 22 should replace “and” with either “an” or “a”, line 24 states “cavity74”, line 32 states, “artifact leaving material 80”, reference numeral 80 previously referred to a composite hub member. Page 12, line 1 states, “cutter tube 21 the hand held”, it appears that “of” should come between 21 and the, additionally reference numeral 21 previously referred to a cutter. Lines 21 and 25 state, “probe 20”; reference numeral 20 previously referred to a needle assembly. Finally Page 13, lines 5 and 13 use “he” instead of “the”.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent

Application Publication 2002/0082519 A1 to Miller et al.

In reference to claims 1 and 9, Miller et al. discloses a biopsy device which is compatible for use with a magnetic resonance imaging machine comprising: a handle (12) and a non-metallic elongated substantially tubular needle [0062] having a proximal end attached to the handle [0056], a distal end extending therefrom, a longitudinal axis therebetween, and a lumen extending therethrough, the needle includes a port (25) for receiving a tissue sample [0059]; a sharpened distal tip (16) for insertion within tissue, the sharpened distal tip attached to the distal end of the needle and at least partially comprising a material which will leave an artifact under magnetic resonance imaging [0062]; and a cutter, movable within the lumen, for obtaining a sample of tissue when the tissue is disposed within the port .

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 3, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent Application Publication 2002/0082519 A1 to Miller et al.

In reference to claims 2, 3, 10 and 11, discloses the needle comprising a non-metallic material of appropriate strength and stiffness [0062] but does not specify the non-metallic material. However, due to the lack of criticality of the material, it would have been obvious to one having ordinary skill in the art to form the needle of any material that meets the desired function. The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0082519 A1 to Miller et al. in view of U.S. Patent No. 5,534,778 to Loos et al.

In reference to claim 12, Miller et al. fails to disclose the material located in the distal tip which will leave an artifact under MRI imaging being selected from the group comprising: gadolinium, titanium, aluminium, copper, brass and bronze. However, Loos et al. discloses a biopsy device compatible for use with a MRI machine wherein the material located in the tip of the needle that leaves an artifact under MRI imaging is gadolinium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal tip of the needle as disclosed by Miller et al. to contain gadolinium as disclosed by Loos et al. in order to check whether or not the tip is located within the area of the tumor (Col. 6, lines 24 – 41) while in use.

7. Claims 1 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,782,764 to Werne in view of U.S. Patent No. 5,534,778 to Loos et al.

In reference to claims 1 and 5, Werne discloses a biopsy device which is compatible for use with a magnetic resonance imaging machine (Figure 2) comprising: a non-metallic elongated (Col. 10, lines 7 – 9) substantially tubular needle (40) having a distal end, a proximal end, a longitudinal axis therebetween, and a port (48) on the elongated needle for receiving a tissue sample (Col. 9, lines

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64 – 67); and a sharpened distal tip (40A) for insertion within tissue, the sharpened distal tip being attached to the distal end of the needle, and a stylet (42) that contains a material which will leave an artifact under magnetic resonance imaging being associated with the distal tip (Col. 61 – 63).

However, Werne fails to disclose the distal tip (40) having a hollow cavity which is at least partially filled with the material which will leave an artifact. However, Loos et al. discloses a biopsy device which is compatible for use with a magnetic resonance imaging machine (Figure 8) wherein the distal tip of the needle has a hollow cavity which is at least partially filled with the material which will leave an artifact (Col. 6, lines 24 – 41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal tip of the needle as disclosed by Werne to contain a hollow cavity filled with the material which will leave an artifact as taught by Loos et al. so that the user can check whether or not the tip is located within the area of the tumor (Col. 6, lines 24 – 41) after the stylet has been removed from the needle.

In reference to claims 2, 3, 6 and 7, Werne discloses the needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 – 65), but fails to disclose the needle comprising a thermoplastic. However it would have been obvious to one having ordinary skill in the art to form the needle of any material that meets the desired function, such as a thermoplastic. The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

In reference to claims 4 and 8, Werne discloses the material which leaves an artifact under magnetic resonance imaging being selected from the group comprising: gadolinium, titanium, aluminum, copper, brass and bronze (Col. 7, lines 24 – 40). Additionally, Loos et al. discloses the material being selected from the group comprising: gadolinium, titanium, aluminum, copper, brass and bronze (Col. 6, lines 24 – 41).

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Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent No. 6,272,370 discloses using thermoplastic in MRI compatible instruments.

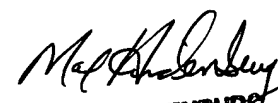
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
March 13, 2003



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700